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10/828,841	04/20/2004	Stephanie M. Kladakis	022956-0259	5305

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EXAMINER	
RICE, BENJAMIN P	

ART UNIT	PAPER NUMBER
3709	

NOTIFICATION DATE	DELIVERY MODE
09/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/828,841	KLADAKIS ET AL.	
	Examiner	Art Unit	
	Benjamin P. Rice	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/26/04, 07/27/05, 10/03/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8, 10-17, 20-21, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Malaviya et al. (US2003/0036797 A1).

With respect to claim 1, Malaviya et al. discloses a biocompatible meniscal repair device (abstract), comprising: a biocompatible tissue repair scaffold (part 250, Fig. 26 and placed in flaps in Fig. 29) adapted to be placed in contact with a defect in a meniscus (part 250 is capable of being placed next to the defect); and a cell growth conduit flap attached to the tissue repair scaffold (Fig 29, part 232 and 234 forming the flaps around part 250), the cell growth conduit flap being adapted to contact a tibial surface and communicate biological materials to a tissue defect in the meniscus (part 234 contacts the tibial surface, and the flaps as a whole have open space to communicate biological materials from the vascularized area in which it contacts, P0024 – Page 4).

With respect to claim 2, Malaviya et al. discloses that the cell growth conduit flap provides a conduit that enables cells and nutrients to travel from the synovium to the tissue repair scaffold and the tissue defect in the meniscus (the flaps in Fig 29 form together a wedged shape conduit in which cells can flow into from the vascularized area, which would enable cells to be able to travel from the synovium to the defect area via bodily fluids as described in P0153).

With respect to claim 3, Malaviya et al. discloses that the cell growth conduit flap is adapted to contact the synovium, as it is capable of being placed next to the synovium. Examiner notes that while Malaviya et al. says the surgeon will generally leave an outer rim (P0134), it does not state that they are required to leave an outer rim, and can thus be placed against the synovium.

With respect to claim 4, Malaviya et al. discloses that the scaffold is made of SIS (small intestine sub mucosa) or other ECM material (P0157), which is known in the art to be bioresorbable.

With respect to claim 5, Malaviya et al. discloses that the compartments which form the scaffold could be made of a biocompatible polymer in substitute of ECM material, or can be made of a composite of the two (P0182, page 17, noting that it says it can be applied to other embodiments of the invention, such as Figure 29). The cell growth conduit flap can be made from an ECM material (P0138). Therefore, the scaffold and the flap can be made from different materials.

With respect to claim 6, Malaviya et al. discloses that both the scaffold and the flap can be made of the same materials (Scaffold made of naturally occurring ECM material – P0157, Flap made of naturally occurring ECM material – P0138).

With respect to claim 7 and 8, Malaviya et al. discloses that the scaffold and cell growth conduit flap include a least one polymer derived from monomers selected from the group consisting of glycolide, lactide, and dioxanone (P0011 states that a mass is filled within the flap space, such as the scaffold and the flap would include within them said mass. P0011 also states in various embodiments the mass can be made of biocompatible polymers, which is later disclosed as glycolide, lactide, dioxanone, and other polymers in P0036. Furthermore, the flap and scaffold could be made in part of these materials as described in P0182.).

With respect to claim 10, Malaviya et al. discloses that the scaffold is made from naturally occurring ECM as explained above with respect to claim 6, which it is inherent that it contains natural polymers.

With respect to claim 11, Malaviya et al. discloses that viable tissue is disposed within the scaffold (biologically derived agents, P0159 – the agents can be tissue as described in P0033). It is inherent that the tissue would integrate with the native tissue.

With respect to claim 12 and 13, Malaviya et al. discloses that the scaffold can contain within it bioactive agents, as stated in P0159. The bioactive agents, described in P0032, can be growth factors or other agents that stimulate cell growth.

With respect to claim 14, Malaviya et al. discloses that the cell growth conduit flap and scaffold can be formed from a single piece, as they both can be made from the same large sheet of ECM material and cut as desired to form the specific parts.

With respect to claim 15-17, Malaviya et al. discloses in Figure 29 that the flap and scaffold are oriented together that they are substantially perpendicular. Furthermore, the scaffold conical sections are capable of being oriented in other directions to form shapes of a "T" or "L".

With respect to claim 20, Malaviya et al. discloses that the cell growth conduit flap appears to have a void volume of 50-95% as shown in Fig. 29.

With respect to claim 21, Malaviya et al. discloses a method of surgically repairing meniscal defects, comprising: providing a tissue repair scaffold having attached thereto a cell growth conduit flap (see explanation above for claim 1); positioning the tissue repair scaffold in contact with a defect in a meniscus while positioning the cell growth conduit flap in contact with a tibial surface (P0024 states that the device is placed in a space where a portion of the meniscus has been removed (the scaffold is in a defect area, and therefore is in contact with the defect), where the cell growth conduit flap would be placed on the tibial surface); and fixing the tissue repair scaffold in position (P0156 explains that the scaffold is placed in position in between the conduit flaps), wherein the cell growth conduit flap allows cells and nutrients to travel to the defect in the meniscus and thereby encourage healing of the meniscus (P0024, page 4 explains that blood and fluid would travel to the inner portion of the device to regenerate the meniscus).

With respect to claim 25 and 27, the above reasoning can be used with respect to claim 21, noting that the cell growth conduit flap is positioned when placing it in the removed area, and the v-shape can be considered the conduit area as the nutrients will travel from the large cross sectional area portion to the small cross sectional area portion, further explained above with respect to claim 2.

3. Claims 1 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Malaviya et al. (US 2004/0143344).

With respect to claim 1, Malaviya et al. discloses a biocompatible meniscal repair device (Abstract, used in meniscal implants – P0045), comprising: a biocompatible tissue repair scaffold (Fig. 9, part 14) adapted to be placed in contact with a defect in a meniscus (Fig. 8 and 8a); and a cell growth conduit flap attached to the tissue repair scaffold (Fig. 9, part 12, layered cover), the cell growth conduit flap being adapted to contact a tibial surface (the cover is capable of being attached to the tibial surface) and communicate biological materials to a tissue defect in the meniscus (part 12 can be made of bioremodelable or ECM material which can communicate biological materials. P0049).

With respect to claim 18, Malaviya et al. discloses that the thickness of the cell growth conduit flap is less than the thickness of the tissue repair scaffold, as clearly shown in Fig. 9.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 9, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. (US 2003/0036797).

With respect to claim 9, Malaviya et al. discloses that the scaffold and flap can include glycolide and L-lactide as explained above with respect to claim 7-8. Malaviya also discloses that any copolymer used in implants can be utilized (P0036). Malaviya does not specifically state that this device uses the copolymer of glycolide and L-lactide. However it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the material with the copolymer of glycolide and L-lactide, as it is well known in the art to use the copolymer of glycolide and L-lactide and Malaviya et al. states that copolymers can be used.

With respect to claim 24 and 26, Malaviya et al. does not explicitly disclose that the cell growth conduit flap is in contact with the synovium. However, Malaviya does state that one or more of the layers of the material forming the upper cover or the lower cover may be formed to provide tabs extending away from the device to facilitate

attachment to the surrounding tissue (end of P0038). This would still be attached and apart of the growth conduit flap, and could extend to the synovium, as it is a surrounding tissue of the meniscus. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the cell growth conduit flap in contact with the synovium, as it would allow for attachment of the device as explained above.

7. Claims 22-23 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. (US 2003/0036797) in view of Li et al. (US 4,790,819).

With respect to claims 22-23 and 28-29, Malaviya et al. does not disclose the step of rasping the meniscus before positioning the cell growth conduit flap. However, Li et al. discloses in the background of the invention, first paragraph, that the initial phase in wound repair is a fibrin clot. They further state that this is absent in meniscal tears, and the synovium and meniscus are rasped to get the blood supply into the area to be able to form a clot (therefore the step would be before positioning any devices in the tear, as it should be the initial phase of the healing). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the step of rasping the meniscus and synovium before placing the cell growth conduit flap in position in view of the teaching of Li et al., as it can provide an increased blood supply to help form a clot and promote wound repair, as explained in the first paragraph of the background of the invention.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. (US 2004/0143344) in view of Malaviya et al. (US 2003/0044444).

With respect to claim 19, Malaviya et al. (US 2004/0143344) discloses that the cell growth conduit flap can be made from ECM material (P0049). Malaviya et al. (US 2004/0143344) does not disclose that the density is in the range of about 150-350 mg/cc. However, Malaviya et al. (US 2003/0044444) discloses an ECM scaffold that can be made to have a desired density (P0035). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ECM material in view of the teaching of Malaviya et al. (US 2003/0044444), as one of ordinary skill in the art would recognize that you could change the densities of the material to suit the needs of the application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Rice whose telephone number is (571) 270-3507. The examiner can normally be reached on Monday - Thursday 7:30am-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrence Till can be reached on (571) 272-1280. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Terrence R. Till
Supervisory Patent Examiner

BR